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In re Application of	:
Gary D. Hogden et al	:
Serial No.: 08/462,703	: PETITION DECISION
Filed: June 5, 1995	:
Attorney Docket No.: SCH1309-C1	:

This is in response to the petition under 37 CFR 1.181, filed December 28, 2005, requesting reversal of an examiner's actions under 37 CFR 1.129(b).

BACKGROUND

A careful review of the file history shows that this application was filed on June 5, 1995, and claims priority to March 2, 1992, and thus qualifies for continuing procedures under 37 CFR 1.129(a).

The application, as filed contained claims 1-27 and claims 28-41 added by preliminary amendment on the date of filing. Independent claim 1 is directed to a method of avoiding bleeding problems associated with administering of estrogen by administering antiprogestin. Independent claim 21 is to a kit containing a months supply of estrogen and antiprogestin tablets. Independent claim 25 is directed to a pharmaceutical composition comprising estrogen and antiprogestin. Independent claim 28 is direted to hormone replacement therapy or fertility control by administering estrogen and antiprogestin. Independent claim 35 is to a method of fertility control using progestin and antiprogestin. The examiner determined that no restriction of the claims was needed and acted on the merits in an Office action mailed September 12, 1995, in which claims 28-31 were rejected under 35 U.S.C. 112, first paragraph for lack of enablement and claims 1-24 and 26-27 were rejected under 35 U.S.C. 112, second paragraph, for indefiniteness. Claims 1-41 were also identified as being in conflict with claims 1-41 of application SN 08/462,705 and claims 28-41 were further rejected under 35 U.S.C. 101 for double patenting.

Applicants replied on December 26, 1995, canceling claims 28-31, but taking no other action. The examiner mailed a Notice of Abandonment to applicants on April 16, 1996, holding the application abandoned for failure to reply to all outstanding issues. A petition for revival under 37 CFR 1.137(b) was filed May 8, 1996, along with a reply to the Office action in which claims 42-81 were added and a request under 37 CFR 1.129(a) was filed. By decision mailed June 21, 1996, the application was revived in view of the amendment, however the filing under 37 CFR

1.129(a) was dismissed as improper as the application was not under Final rejection. A supplemental amendment under 37 CFR 1.115 was filed July 19, 1996, which canceled claims 1-27, added claims 82-107 and further amended claims 42 and 48-49. Applicants, however, identify only claims 42-107 as being present in the application. Independent claim 42 is directed to a method of hormone replacement therapy or contraception by administering estrogen, progestin and antiprogestin to ameliorate uterine bleeding control. Independent claim 49 is directed to administering progestin and antiprogestin to ameliorate uterine bleeding control. Independent claims 56, 61, 67, 72, 77 and 82 are to a method of hormone replacement therapy by administering estrogen and antiprogestin to inhibit bleeding and other conditions. Independent claim 102 is to a kit containing estrogen and progestin and antiprogestin containing tablets. Independent claim 104 is to a pharmaceutical composition comprising estrogen, progestin and antiprogestin. A supplemental amendment on March 4, 1997, canceled claims 32-41.

The examiner mailed a Final Office action to applicants on March 17, 1997, rejecting claims 42-55 and 102-107 under 35 U.S.C. 103(a) as unpatentable over Hogden in view of Black. Claims 556-81 were rejected for obvious double patenting over US 5,468,736. Claims 42-107 were indicated as conflicting with claims 42-107 of SN 08/462,705 and a request was made to eliminate the overlapping claims from one of the applications. Applicants replied by filing a Notice of Appeal on September 17, 1997.

Applicants filed a formal reply on April 17, 1998, amending claims 42 and 49, and requesting a first reopening of prosecution under 37 CFR 1.129(a). The examiner mailed a non-Final Office action to applicants on June 9, 1998, again rejecting claims 42-55 and 102-107 under 35 U.S.C. 103(a) as unpatentable over Hogden in view of Black. Claims 56-81 were rejected for obvious double patenting on US 5.468,736 and claims 42-107 were deemed to be in conflict with claims 42-107 of SN 08/462,705 again.

Applicants replied on December 9, 1998, noting that the patent over which the obvious double patenting rejection was made was not commonly owned and a terminal disclaimer was not appropriate. Applicants also offered a brief explanation as to why the claims of this application and SN 08/462,705 (and also SN 08/115,008) were being allowed to remain in conflict with US 5,468,736 (and also US 5,516,769, US 5,622,943, and US 5,439,913). No amendments were made.

The examiner mailed a new non-Final Office action to applicants on March 4, 1999, setting forth the same rejections as before, changing only the claim numbers to which the obvious double patenting rejection applied to claims 42-46, 56-81, 94 and 98-99. Applicants replied on September 9, 1999, making only a brief argument with respect to the rejection under 35 U.S.C. 103(a).

The examiner mailed a Final Office action to applicants on December 6, 1999, repeating all of the rejections and objections of the previous Office action and responding to applicants' brief arguments properly. Applicants filed a Notice of Appeal on June 6, 2000. Applicants then filed a second request under 37 CFR 1.129(a) on January 8, 2001, along with a formal reply to the last Office action. A telephonic interview was held with an examiner newly assigned to the application on February 20, 2001.

The new examiner mailed a non-Final Office action to applicants on May 22, 2001, setting forth the same rejections and objections for the same reasons as in the previous Final Office action of December 6, 1999. Applicants replied on November 21, 2001, by responding to each rejection and objection in the same manner as previously. No new arguments were offered.

The examiner mailed an Office action to applicants on March 5, 2002, setting forth a restriction requirement between claims 42-101 and claims 102-107, method of use and composition/product claims. The examiner also set forth various election of species requirements with respect to the two groups. Applicants, in filing a reply on June 13, 2002, while complying with the requirements of the Office action, protested that the imposition of a restriction requirement was improper for various reasons. Applicants also indicated that interference proceedings were in preparation between this application and US 5,622,943 and US 5,468,736.

The examiner mailed a non-Final Office action to applicants on October 3, 2002, indicating that applicants' election was incomplete in that no election of species was made. Applicants replied on December 3, 2002 by formalizing the election of species and continuing the traversal previously set forth.

The examiner mailed a non-Final Office action to applicants on April 28, 2003, responding to applicants' traversal, but maintaining the requirement and rejecting claims 49-50 and 55 under 35 U.S.C. 102(e) over Hogden. Applicants replied on May 22, 2003, requesting that an interference be instituted.

The examiner mailed a new Office action to applicants on October 27, 2004, rejecting claims 49-50 and 55 under 35 U.S.C. 112, second paragraph, as indefinite and claim 49 for obvious double patenting over US 5,622,943. Applicants replied on April 17, 2005, responding to each of the rejections.

An Office action was mailed to applicants on December 6, 2005, setting forth requirements for suggesting an interference and setting a time period of one month, not extendable under 37 CFR 1.136(a), for compliance. Applicants filed a supplemental amendment on December 28, 2005, a request for a one month extension of time under 37 CFR 1.136(b) (which has been granted) and this petition. The supplemental amendment cancels claims 77-81 and 106-107 and adds claims 108-134. Independent claim 108 is directed to a method of avoiding bleeding problems associated with administration of estrogen and antiprogestin. Independent claim 128 is directed to a kit containing estrogen/progestin tablets and an antiprogesstin tablet. Independent claim 132 is to a pharmaceutical composition containing estrogen, progestin and antiprogestin. The added claims are indicated as being identical to the originally presented claims.

DISCUSSION

Applicants' petition is directed to application of 37 CFR 1.129(b)(1) and (2). Part (1) of the rule states that no requirement for restriction shall be made in an application pending on June 8, 1995, which has been pending for at least three years (including claims of priority to parent applications) except where (A) the requirement was made in this or an earlier application prior to

April 8, 1995, (B) the requirement could not have been made due to actions by applicant, or (C) the fees have not been paid for examination of additional inventions. Part (2) or the rule permits applicants to pay additional fees for examination of additional inventions following the imposition of a proper restriction requirement.

As this application was filed prior to June 8, 1995, and claims priority to applications filed in March, 1992, more than three years earlier, the provisions of 37 CFR 1.129(b) apply. Applicants have availed themselves of the provisions of 37 CFR 1.129(a) by twice filing a request to reopen prosecution following a Final Office action and have thus exhausted any further remedy thereunder. Following the second reopening of prosecution the second examiner set forth a restriction requirement and an election of species requirement. The requirement was based on claims which were virtually unamended since the reply to the first Office action was filed. The requirement divided method of use claims from composition and kit claims. The election of species was directed to selecting among various protocols of administration present in the claims. However, 37 CFR 1.129(b) essentially prohibits making a restriction requirement among such pending claims, or, if one is made, permits applicants to pay additional fees to have all inventions examined.

Applicants petition requests the Office to take appropriate action in view of the above rule and circumstances surrounding prosecution of this application. Based on the prosecution history where the first examiner concluded that all claims were related to each other and not directed to independent and distinct inventions and the second examiner initially did the same, it is concluded that the restriction requirement imposed on applicants, as well as the election of species requirement, were improper. It is Office policy that a set of claims which has been prosecuted together and to which no substantive amendments have been made should not at a later date be divided into separate inventions. Such amounts to imposing duplication of effort on the Office as well as applicants. In view of the above, the restriction requirement is withdrawn as improper.

DECISION

The petition is **GRANTED**. **The restriction requirement imposed by the examiner is withdrawn. All claims will be examined and are considered subject to any rejections set forth in the Office action mailed May 22, 2001, which have subsequently not been indicated as being overcome.**

However, in view of the length of prosecution of this application and applicants' request for an interference proceeding to be instituted, applicants will remain under obligation to reply to the Office action mailed December 6, 2005, within the time period, as extended, set.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.

Bruce M. Kisliuk
Director, Technology Center 1600